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*Admitted only in Maryland
+ Admitted only in Virginia
•Practice Limited to
Federal Agencies

June 8, 2004

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Art Unit 1646

Re: U.S. Utility Patent Application
Appl. No. 10/774,622; Filed: February 10, 2004
For: **Death Domain Containing Receptor 5**
Inventors: NI *et al.*
Our Ref: 1488.131000D/EKS/EJH

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;
2. Form PTO-1449 (19 sheets citing 65 documents); and
3. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

EJH/M-M:amr

258529.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Ni *et al.*

Appl. No.: 10/774,622

Filed: February 10, 2004

For: Death Domain Containing Receptor 5

Confirmation No.: 9532

Art Unit: 1646

Examiner: *To be assigned*

Atty. Docket: 1488.131000D/EKS/EJH

First Supplemental Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on February 10, 2004, in connection with the above-captioned application.

Copies of the documents were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/042,583 which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of the documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner is referred to the following related, co-pending patent applications:

U.S. Patent Application No. 10/005,842, filed December 7, 2001, inventors Ni *et al.*,
Pub. No. US 2002/0098550 A1, listed herein as Document AE1;

U.S. Patent Application No. 10/648,825, filed August 27, 2003, inventors Ni *et al.*, cited
as Document AS33.

The Examiner's attention is also directed to the following recently issued U.S. Patent directed to related subject matter: U.S. Patent No. 6,743,625 issued June 1, 2004, and cited as document **AE2**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

Date: June 8, 2004

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253901.1

FORM PTO-1449

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
1488.131000D/EKS/EJH/M-MAPPLICATION NO.
10/774,622FIRST NAMED INVENTOR
Ni et al.FILING DATE
February 10, 2004ART UNIT
1646**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA						
AB						
AC						
AD2	2002/0098550 A1	07/25/2002	Ni et al.			12/07/2001
AE2	6,743,625	06/01/2004	Ni et al.			06/06/2001
AF2	6,461,823	10/08/2002	Ni et al.			11/24/1999
AG2	6,342,363	01/29/2002	Ni et al.			01/27/1998
AH2	6,433,147	08/13/2002	Ni et al.			05/05/2000
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL4	WO 98/41629 A2 & A3	09/24/1998	WIPO			Yes No
AM4	EP 1 181 319 A0	12/07/2000	Europe			Yes No
AN4	EP 1 192 185 A0	12/14/2000	Europe			Yes No
AO4	EP 1 287 035 A1	03/05/2003	Europe			Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>15</u>	Allison, J., et al., "Transgenic expression of CD95 ligand on islet β cells induces a granulocytic infiltration but does not confer immune privilege upon islet allografts," <i>Proc. Natl. Acad. Sci. USA</i> 94:3943-3947, National Academy Press (April 1997)
AS	<u>15</u>	Allison, J., and Strasser, A., "Mechanisms of β cell death in diabetes: A minor role for CD95," <i>Proc. Natl. Acad. Sci. USA</i> 95:13818-13822, National Academy Press (November 1998)
AT	<u>15</u>	Bodmer, J.-L., et al., "TRAMP, a Novel Apoptosis-Mediating Receptor with Sequence Homology to Tumor Necrosis Factor Receptor 1 and Fas(Apo-1/CD95)," <i>Immunity</i> 6:79-88, Cell Press (January 1997)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

O I P E JUN 08 2004 JC25 FORM PTO-146 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1488.131000D/EKS/EJH/M-M	APPLICATION NO. 10/774,622
		FIRST NAMED INVENTOR Ni et al.	
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AL						Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>16</u>	Boldin, M.P., et al., "A Novel Protein That Interacts with the Death Domain of Fas/APO1 Contains a Sequence Motif Related to the Death Domain," <i>J. Biol. Chem.</i> 270:7795-7798, American Society for Biochemistry and Molecular Biology, Inc. (1995)
AS	<u>16</u>	Chicheportiche, Y., et al., "TWEAK, a New Secreted Ligand in the Tumor Necrosis Factor Family That Weakly Induces Apoptosis," <i>J. Biol. Chem.</i> 272:32401-32410, American Society for Biochemistry and Molecular Biology, Inc. (December 1997)
AT	<u>16</u>	Chinnaiyan, A.M., et al., "FADD, a Novel Death Domain-Containing Protein, Interacts with the Death Domain of Fas and Initiates Apoptosis," <i>Cell</i> 81:505-512, Cell Press (1995)

EXAMINER	DATE CONSIDERED
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O I P E JUN 8 2004 S2 FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRADEMARK OFFICE		ATTY. DOCKET NO. 1488.131000D/EKS/EJH/M-M	APPLICATION NO. 10/774,622
		FIRST NAMED INVENTOR Ni et al.	
		FILING DATE February 10, 2004	ART UNIT 1646

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AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	17	Clerici, M., et al., "Type 1 and Type 2 Cytokines in HIV Infection - A Possible Role in Apoptosis and Disease Progression," <i>Ann. Med.</i> 29:185-188, Finnish Medical Society DUODECIM (June 1997)
AS	17	Degli-Esposti, M.A., et al., "Cloning and Characterization of TRAIL-R3, a Novel Member of the Emerging TRAIL Receptor Family," <i>J. Exp. Med.</i> 186:1165-1170, Rockefeller University Press (October 1997)
AT	17	Degli-Esposti, M.A., et al., "The Novel Receptor TRAIL-R4 Induces NF-κB and Protects against TRAIL-Mediated Apoptosis, yet Retains an Incomplete Death Domain," <i>Immunity</i> 7:813-820, Cell Press (December 1997)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>18</u>	Duan, H. and Dixit, V.M., "RAIDD is a new 'death' adaptor molecule," <i>Nature</i> 385:86-89, Macmillan Publishers, Ltd. (January 1997)
AS	<u>18</u>	Frankfurt, O.S., et al., "Protection from Apoptotic Cell Death by Interleukin-4 is Increased in Previously Treated Chronic Lymphocytic Leukemia Patients," <i>Leuk. Res.</i> 21:9-16, Elsevier Science, Ltd (January 1997)
AT	<u>18</u>	Gooch, J.L., et al., "Interleukin 4 Inhibits Growth and Induces Apoptosis in Human Breast Cancer Cells," <i>Cancer Res.</i> 58:4199-4205, American Association for Cancer Research (September 1998)

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	AL						Yes
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	AP						Yes
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>19</u>	Grell, M., et al., "Induction of cell death by tumour necrosis factor (TNF) receptor 2, CD40 and CD30: a role for TNF-R1 activation by endogenous membrane-anchored TNF," <i>EMBO J.</i> 18:3034-3043, Oxford University Press (June 1999)
AS	<u>19</u>	Hardiman, G., et al., "Genetic Structure and Chromosomal Mapping of MyD88," <i>Genomics</i> 45:332-339, Academic Press (October 1997)
AT	<u>19</u>	Hildeman, D.A., et al., "Activated T Cell Death In Vivo Mediated by Proapoptotic Bcl-2 Family Member Bim," <i>Immunity</i> 16:759-767, Cell Press (June 2002)

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FORM PTO-1449 <u>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</u>			ATTY. DOCKET NO. 1488.131000D/EKS/EJH/M-M	APPLICATION NO. 10/774,622
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>20</u>	Hill, M.E., et al., "Prognostic Significance of BCL-2 Expression and <i>bcl-2</i> Major Breakpoint Region Rearrangement in Diffuse Large Cell Non-Hodgkin's Lymphoma: A British National Lymphoma Investigation Study," <i>Blood</i> 88:1046-105, American Society of Hematology (August 1996)
AS	<u>20</u>	Ho, Y.S., et al., "Brain acetylhydrolase that inactivates platelet-activating factor is a G-protein-like trimer," <i>Nature</i> 385:89-93, Macmillan Publishers, Ltd. (January 1997)
AT	<u>20</u>	Hofmann, K., and Bucher, P., "The CARD domain: a new apoptotic signalling motif," <i>Trends Biochem. Sci.</i> 22:155-156, Elsevier Science, Ltd. (May 1997)

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AL						Yes No
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AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>21</u>	Horigome, A., et al., "Tacrolimus-induced apoptosis and its prevention by interleukins in mitogen-activated human peripheral-blood mononuclear cells," <i>Immunopharmacology</i> 39:21-30, Elsevier Science B.V. (March 1998)
AS	<u>21</u>	Hsu, H., et al., "TRADD-TRAF2 and TRADD-FADD Interactions Define Two Distinct TNF Receptor 1 Signal Transduction Pathways," <i>Cell</i> 84:299-308, Cell Press (January 1996)
AT	<u>21</u>	Huang, D.C.S., et al., "Activation of Fas by FasL induces apoptosis by a mechanism that cannot be blocked by Bcl-2 or Bcl-x _L ," <i>Proc. Natl. Acad. Sci. USA</i> 96:14871-14876, National Academy Press (December 1999)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>22</u>	Huang, D.C.S., et al., "Bcl-2, Bcl-x _L and adenovirus protein E1B19kD are functionally equivalent in their ability to inhibit cell death," <i>Oncogene</i> 14:405-414, Stockton Press (January 1997)
AS	<u>22</u>	Irmiger, M., et al., "Direct physical interaction between the <i>Caenorhabditis elegans</i> 'death proteins' CED-3 and CED-4," <i>FEBS Lett.</i> 406:189-190, Elsevier Science B.V. (April 1997)
AT	<u>22</u>	Irmiger, M., et al., "Inhibition of death receptor signals by cellular FLIP," <i>Nature</i> 388:190-195, Macmillan Publishers, Ltd. (July 1997)

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AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>23</u>	Karin, M., and Lin, A., " NF-κB at the crossroads of life and death," <i>Nat. Immunol.</i> 3:221-227, Nature Publishing Group (March 2002)
AS	<u>23</u>	Kelliher, M.A., et al., "The Death Domain Kinase RIP Mediates the TNF-Induced NF-κB Signal," <i>Immunity</i> 8:297-303, Cell Press (March 1998)
AT	<u>23</u>	Lindner, H., et al., "Peripheral Blood Mononuclear Cells Induce Programmed Cell Death in Human Endothelial Cells and May Prevent Repair: Role of Cytokines," <i>Blood</i> 89:1931-1938, American Society of Hematology (March 1997)

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AR	<u>24</u>	Lotem, J., and Sachs, L., "Hematopoietic Cytokines Inhibit Apoptosis Induced by Transforming Growth Factor β 1 and Cancer Chemotherapy Compounds in Myeloid Leukemic Cells," <i>Blood</i> 80:1750-1757, American Society of Hematology (1992)
AS	<u>24</u>	Lotem, J., and Sachs, L., "Interferon- γ inhibits apoptosis induced by wild-type p53, cytotoxic anti-cancer agents and viability factor deprivation in myeloid cells," <i>Leukemia</i> 9:685-692, Stockton Press (1995)
AT	<u>24</u>	MacFarlane, M., et al., "Identification and Molecular Cloning of Two Novel Receptors for the Cytotoxic Ligand TRAIL," <i>J. Biol. Chem.</i> 272:25417-25420, American Society for Biochemistry and Molecular Biology, Inc. (October 1997)

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AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	25	Muzio, M., et al., "FLICE, a Novel FADD-Homologous ICE/CED-3-like Protease, Is Recruited to the CD95 (Fas/APO-1) Death-Inducing Signaling Complex," <i>Cell</i> 85:817-827, Cell Press (June 1996)
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FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT			ATTY. DOCKET NO. 1488.131000D/EKS/EJH/M-M	APPLICATION NO. 10/774,622
			FIRST NAMED INVENTOR Ni et al.	FILING DATE February 10, 2004

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AR	<u>26</u>	Newton, K., et al., "FADD/MORT1 regulates the pre-TCR checkpoint and can function as a tumour suppressor," <i>EMBO J.</i> 19:931-941, Oxford University Press (March 2000)
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AT	<u>26</u>	Newton, K., and Strasser, A., "Ionizing Radiation and Chemotherapeutic Drugs Induce Apoptosis in Lymphocytes in the Absence of Fas or FACC/MORT1 Signaling: Implications for Cancer Therapy," <i>J. Exp. Med.</i> 191:195-200, Rockefeller University Press (January 2000)

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AR	<u>28</u>	Pan, G., et al., "TRUNDD, a new member of the TRAIL receptor family that antagonizes TRAIL signalling," <i>FEBS Lett.</i> 424:41-45, Elsevier Science B.V. (March 1998)
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AT	<u>28</u>	Shadmehr, R., and Holcomb, H.H., "Neural Correlates of Motor Memory Consolidation," <i>Science</i> 277:821-825, American Association for the Advancement of Science (August 1997)

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AR	<u>29</u>	Simonitsch, I., and Krupitza, G., "Autocrine self-elimination of cultured ovarian cancer cells by tumour necrosis factor α (TNF- α)," <i>Br. J. Cancer</i> 78:862-870, Nature Publishing Group on behalf of Cancer Research, UK (October 1998)
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AR	<u>30</u>	Thome, M., et al., "Viral FLICE-inhibitory proteins (FLIPs) prevent apoptosis induced by death receptors," <i>Nature</i> 386:517-521, Macmillan Publishers, Ltd. (April 1997)
AS	<u>30</u>	Villunger, A., et al., "Fas Ligand, Bcl-2, Granulocyte Colony-Stimulating Factor, and p38 Mitogen-activated Protein Kinase: Regulators of Distinct Cell Death and Survival Pathways in Granulocytes," <i>J. Exp. Med.</i> 192:647-657, Rockefeller University Press (September 2000)
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AR	<u>31</u>	Walczak, H., et al., "TRAIL-R2: a novel apoptosis-mediating receptor for TRAIL," <i>EMBO J.</i> 16:5386-5397, Oxford University Press (September 1997)
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AR	<u>32</u>	Yoshida, T., et al., "Rapid B cell apoptosis induced by antigen receptor ligation does not require Fas (CD95/APO-1), the adaptor protein FADD/MORT1 or CrmA-sensitive caspases but is defective in both MRL-+/+ and MRL-lpr/lpr mice," <i>Int. Immunol.</i> 12:517-526, Japanese Society for Immunology (April 2000)
AS	<u>32</u>	Zou, W., et al., "Administration of Interleukin 13 to Simian Immunodeficiency Virus-Infected Macaques: Induction of Intestinal Epithelial Atrophy," <i>AIDS Res Hum Retroviruses</i> 14:775-793, Mary Ann Liebert, Inc. (June 1998)
AT	<u>32</u>	European Search Report for European Application No. EP 00 93 0329 mailed on February 6, 2004, Munich, Germany

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AR	<u>33</u>	Co-Pending U.S. Patent Application No. 10/005,842, inventors Ni et al., filed December 7, 2001, now U.S. Published Patent Application No. 2002/0098550 (Document AD2)
AS	<u>33</u>	Copy of co-pending U.S. Application No. 10/648,825, inventors Ni et al., filed August 27, 2003
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